

## REMARKS

### *The Present Invention*

The present invention is directed to a novel W/O/W type oil adjuvant for a vaccine comprising (a) an inner aqueous phase, (b) an oil component phase which is in a liquid state at a temperature in the range of 15-25 °C, and (c) an outer aqueous phase comprising 0.5 - 20 wt% of a polyethylene glycol derivative of formula (I) having a molecular weight of 400 - 20,000.

### *The Pending Claims*

Claims 1-17 are currently pending.

### *The Amendments to the Claims*

Claims 1-17 have been amended to point out more particularly and claim more distinctly the present invention. Specifically, the claims have been amended to recite a W/O/W type oil adjuvant for a vaccine. In addition, since the claims are directed to an adjuvant and a method of preparing the adjuvant, the recitation of an antigen component has been removed from claims 1, 4, and 5. Finally, claim 1 has been amended to delete the phrase "and wherein the inner aqueous phase is discontinuous and suspended in the oil component phase, and the oil component phase is discontinuous and suspended in the outer aqueous phase." No new matter has been added by way of these amendments.

### *The Office Action*

The Office has rejected claims 1-17 under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement. Claims 1-17 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey that applicants had possession of the claimed invention. Finally, claims 1-17 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing new matter. Reconsideration of these rejections is hereby requested.

### *Discussion of the Enablement Rejection*

The Office Action rejects claims 1-17 under Section 112, first paragraph, for allegedly failing to enable the skilled artisan to practice the full scope of the claimed invention without undue experimentation. More specifically, the Office contends that the specification provides insufficient evidence that the claimed vaccine could function for the treatment or prevention of the diseases/conditions that would be encompassed by the claims.

Claims 1-17 have been amended to recite a W/O/W type oil adjuvant for a vaccine. The oil adjuvant comprises: (a) an inner aqueous phase, (b) an oil component phase which is in a liquid state at a temperature in the range of 15-25 °C, and (c) an outer aqueous phase comprising 0.5 - 20 wt% of a polyethylene glycol derivative of formula (I) having a molecular weight of 400 - 20,000. In view of the amendment, it is submitted that the enablement rejection has been overcome.

As stated before, the present application teaches one of ordinary skill in the art how to make and use the oil adjuvant for a vaccine of the pending claims. Such teaching pertains to the types of materials suitable for the inner aqueous phase, oil phase, outer aqueous phase, and the PEG component (see, for example, specification page 4, line 37 – page 7, line 5). A general method for preparing the oil adjuvant for a vaccine is provided at, for example, specification page 14, lines 22-33. Specific methods of preparing the oil adjuvant of the present invention are found at, for example, specification page 14, line 34- page 17, line 9. In addition, the specification definitively teaches how to use the oil adjuvant for a vaccine (see, for example, specification page 21, line 1 – page 29, line 1). Moreover, the Office admits that the oil adjuvant of claims 1-17 is enabled by the specification (see Office Action, page 6, third paragraph).

#### *Discussion of the Written Description Rejection*

The Office contends that claims 1-17 contain subject matter that was not described in the specification in such a way as to reasonably convey that applicants had possession of the claimed invention. In particular, the Office alleges that the specification discloses a single vaccine, which cannot be considered to be representative of the number of species claimed by the genus of vaccines. In view of the amendment to claims 1-17, it is submitted that the written description rejection has been overcome.

Specifically, amended claims 1-17 recite a W/O/W type oil adjuvant for a vaccine comprising: (a) an inner aqueous phase, (b) an oil component phase which is in a liquid state at a temperature in the range of 15-25 °C, and (c) an outer aqueous phase comprising 0.5 - 20 wt% of a polyethylene glycol derivative of formula (I) having a molecular weight of 400 - 20,000. The present application contains multiple examples of suitable reagents, a general method of preparing the oil adjuvant for vaccine, and many specific examples of the present inventive W/O/W type oil adjuvant. Accordingly, the subject matter of claims 1-17 is amply

In re Appln. of Saito et al.  
Application No. 09/706,301

described in the specification of the present application in such a way as to reasonably convey that applicants had possession of the invention as defined by the pending claims.

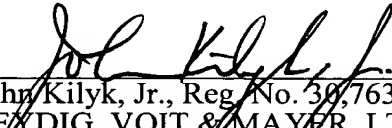
*Discussion of the New Matter Rejection*

According to the Office, the phrase "discontinuous and suspended" is not supported by the specification. Since this phrase is inherent to the W/O/W type oil adjuvant recited in claims 1-17, this phrase has been deleted from the pending claims. In view of this amendment, it is submitted that the new matter rejection has been overcome.

*Conclusion*

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

  
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